Carcinogen Regulation: Risk Characteristics and the Synthetic Risk Bias

by

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Why does the government regulate different kinds of risks? Economists usually trace the motivation to the regulation to the existence of some form of market failure. In such instances, it will be desirable to regulate substances for which the benefits of the regulation exceed the costs, which will potentially be the case if there is some inadequacy in the market.

The restrictive legislative mandates of regulatory agencies in some cases prohibit basing regulations on a balancing of benefits and costs, and, at the very least, seldom encourage such **balancing.**[1] As a result, one would expect the benefits of regulatory efforts to play a greater role in regulatory decisions than do the **costs.**[2] This pattern is exemplified by the high implicit values per statistical life that have been observed for U.S. regulatory **efforts.**[3] Regulatory agencies consequently tend to be risk-oriented in their policy approach.

What this characterization neglects is that even within the context of emphasizing risks, regulatory agencies may not be making balanced decisions. The risk level consists of two principal components, the probability of an adverse outcome and the number of people affected. The probability depends on the potency of the exposure, the frequency of the exposure, and similar kinds of parameters. Regulatory agencies are generally concerned with the risk, particularly with respect to the potency of the chemicals. In contrast, the number of people exposed to

the risk plays a much less prominent role in regulatory decisions. The standard regulatory policy trigger is typically linked to a probability of an adverse outcome as opposed to an expected body count.

The U.S. Environmental Agency Superfund program is a case in point. In that effort, the focus is on the risks posed by different pathways by which populations could be exposed to the hazard. In the course of the detailed policy analysis prepared for each Superfund site, EPA never assesses the size of the population exposed to the risk. Moreover, there is not even an assessment of the probability that a future population will be exposed to the risk. The presence of a risk with a potential exposure to a future population is sufficient to trigger government action.

Extrapolation from this experience to other instances would lead one to expect that the probability of cancer or some other adverse health outcome would be the driving force behind regulatory decisions. However, even this characterization may be overly broad. In this paper I will explore the decision to regulate natural and synthetic chemicals. To what extent are regulatory decisions driven by the severity of the risk as opposed to the character of the risk exposure? The striking result is that the risk severity plays very little role. Instead, it is whether the chemical is synthetic or natural that is the driving force behind regulatory decisions.

I. The Carcinogen Sample

The results here will focus on a sample of widely publicized carcinogens developed by Bruce N. Ames and discussed in Bruce Ames, Margie Profet, and Lois Swirsky (1990) and in Lois Gold, et al. (1992). These results are similar to those obtained for a much larger sample of several hundred chemicals in a study by the author.

The particular chemical sample that will be analyzed consists of 51 different chemicals that appear in 80 potential sources, which I will designate as the Ames 51 and Ames 80 samples. Many of the potential chemical exposures are to common natural products, such as lettuce, basil, brown mustard, celery, and coffee. In addition, there are exposure to other chemicals such as Captan, Lindane, and DDT. The chemicals may appear more than one time in the listing because they may occur in multiple products. For example, caffeic acid is a carcinogen contained in lettuce, apples, pears, coffee, plums, celery, carrots, and potatoes.

For each of these chemicals, Ames developed indices of the carcinogenicity of the chemical. The primary risk measure of the hazard, which reflects both the potency of the chemical as well as the amount of the daily human exposure, is the human exposure/rodent potency index (HERP). For the chemical group, the highest possible HERP index is 140 for exposures to EDB, with the lowest being $\mathbf{6x10^{-9}}$ for Captan.

Ames has also developed a carcinogenic potency database to capture the riskiness of carcinogens independent of the extent of

human exposure. The two measures that will be analyzed in this paper are the TD_{50} values for rats and mice. The TD_{50} value is the chronic dose (in mg/kg-day) of the chemical which causes half of the rats (mice) in the sample to develop tumors over the course of a lifetime. Chemicals with higher TD_{50} values are consequently safer than those with lower values. The HERP value calculated for each exposure has been obtained using the more sensitive of the two species to calculate the possible risk implied by the chemical exposure. Other risk measures, such as the EPA IRIS data base slope factors, generate similar results.

The other principal characteristic of chemicals that will be assessed is the extent to which chemicals that are synthetic (0-1 dummy variable) are regulated more or less stringently than those that are not. Synthetic chemicals are subject to the Delaney Clause so that one would expect synthetic food additives to be subject to more stringent regulation. However, the pattern for synthetic chemicals proves to be quite general and is apparent across different agencies as well. If agencies are truly concerned with the actual risks posed by the chemicals, they should not be concerned with their synthetic nature but instead should focus on the magnitude of the risk based on the HERP index or some other measure of potency. An alternative possibility is that it is not simply the magnitude of the risk that is consequential, but also the character of the risk. The general public, for example, greatly overestimates novel risks such as those associated with synthetic chemicals. To the extent that

regulatory agencies are reflective of public preferences, one would expect there to be more stringent regulation of synthetic chemicals.

II. Patterns of Regulation

Table 1 summarizes the different patterns of regulation. For the Ames 51 sample, 35 of the chemical exposures are regulated, and 16 are not. For the Ames 80 sample, 49 exposures are regulated and 31 are not. Thus, in each case the sample is comprised of a very large number of regulated chemicals.

Table 1 presents information for these chemicals based on all regulations of the chemicals as well as those subject to FDA regulation. In each case, the top panel of Table 1 provides information by regulatory status of the chemicals of the average percentage of chemicals that are synthetic and the risks associated with them. It is particularly striking that the regulated chemicals are disproportionately synthetic. In the Ames 51 sample, 63 percent of the regulated chemicals are synthetic, and 13 percent of the unregulated chemicals are synthetic. Similar patterns are displayed in the Ames 80 group as well. A similar synthetic emphasis with an even higher percentage of regulated chemicals being synthetic is captured in the FDA regulation group.

Whereas the synthetic status of the chemical plays a pivotal role in determining regulatory decisions, the risk level is not. The natural log of the HERP index is the measure of the risk level that is used. Because of the role of very high risk

outliers, particularly EDB exposures which have a HERP value almost an order of magnitude larger than the second largest chemical exposure examined, the natural logarithm of the risk is used to capture the risk level. Somewhat strikingly, from both the Ames 51 and Ames 80 group and for Federal regulations overall and FDA regulations, the Ln(HERP index) has a lower value for the regulated chemicals than for unregulated chemicals. In terms of the risk level, the regulated chemicals pose a somewhat lower risk using this index, whereas they differ considerably in terms of their synthetic character, as they are disproportionately synthetic.

The breakdown at the bottom of Table 1 provides an even more striking contrast. For the Ames 51 sample, 24 of the 51 chemicals are synthetic, and for the Ames 80 sample, 31 of the 80 chemicals are synthetic. In each instance, over 90 percent of the synthetic chemicals are the subject of Federal regulation, as compared with under half of the non-synthetic. Moreover, the risks posed by synthetic chemicals as measured by the Ln(HERP index) are lower for the synthetic chemicals than the non-synthetic chemicals. Similar contrast is evident in the case of FDA regulations, which capture a smaller segment of the chemical group but for which there is an even greater relative contrast between the synthetic and non-synthetic chemicals in terms of the probability of regulation. As in the case of all chemicals, the risk levels posed by the synthetic chemicals are a bit less than for those that are not synthetic.

These results also are borne out in more detailed logit regression results to assess the determinants of the probability of government regulation. Each equation includes characterizations of the synthetic character of the risk and a measure of the risk level -- either the HERP index or the TD_{50} values for rats and mice. Sensitivity analyses with a wide variety of risk measures and functional forms for these risk measures yielded similar results. Moreover, these regressions also control for the presence of test information with respect to the different chemicals.

The principal pattern characterized by the results in Table 2 is that the synthetic character of the risk is a driving force behind the probability of regulation, controlling for the risk level. Although the results differ somewhat across specifications, overall the synthetic character of the chemical for this sample increases the probability of regulation by an average of about one-third. One would expect for a sample of much less potent carcinogens that this influence would be less. It is also striking that none of the other risk measures included in the equation are ever statistically significant at the usual confidence levels. For the range of variation of riskiness reflected in this sample, it is not the risk posed by the chemicals but rather the character of the risk that seems to be most instrumental in driving Federal regulatory decisions.

III. Explaining Regulatory Patterns

Once government agencies depart from a framework in which

the total net benefits of regulations become a matter of concern, there is no assurance that the overall risk effects will be captured in the decisions. Agency practices suggest that there is undue emphasis on the probabilities involved rather than the populations exposed.

What this examination of carcinogen regulation indicates is that the character of the risks is instrumental as well. For the chemical groups considered, it is not the magnitude of the risk but rather the synthetic nature of the risks that drives the regulatory decision. This type of bias by government agencies appears to be reflective of a similar irrationality on the part of individual decisions.

One of the principal anomalies that has been documented in the risk perception and choice under uncertainty literature is that individuals tend to overreact to increases in the risk level. W. Kip Viscusi, Wesley A. Magat, and Joel Huber (1987) have termed this a "reference risk" effect whereby changes in the risk level from the accustomed risk will lead to an exaggerated response in terms of the implicit risk-dollar tradeoff reflected in individual decisions. Focusing on a similar line of argument, William Samuelson and Richard J. Zeckhauser (1988) term such behavior a "status quo bias."

Policies based on the synthetic character of chemicals embody these kinds of influences. Chemicals that generate hazardous exposures because they are a natural part of our environment are much more readily accepted than those that are

synthetic. One possible explanation is that there is an implicit judgement on the part of the public and by government agencies that the cost of eliminating natural carcinogens are much greater than the costs associated with avoiding synthetic chemicals. However, such explanations do not appear to be fully persuasive. For example, the government can certainly ban peanut butter so that we could avoid aflatoxin exposures if we were truly concerned with risk levels since the major cost would be forgoing use of this hazardous product rather than threatening the well-being of the U.S. economy. Moreover, to the extent that the official regulatory biases have been embodied in legislation or agency directives it is the specific synthetic character of the chemical that is the pertinent regulatory concern rather than its linkage to cost-risk tradeoffs or other factors that might be of greater concern to economists.

These findings suggest that consumers participating in hypothetical experiments and students who have responded to the various laboratory experiments are not alone in their overreaction to increases in the accustomed risk level. The Federal government appears to have institutionalized these biases in the course of developing its regulation of synthetic chemicals. Whereas the appropriate task of the government is to alleviate market failures, in this instance its principal function has been to institutionalize them.

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Footnotes

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1. See for example, the discussion in W. Kip Viscusi (1992).

2. This does not mean that costs are unimportant. See Maureen Cropper, et al. (1992).

3. For review, see John Morrall (1986) and W. Kip Viscusi (1992).

Table 1

Summary of Key Risk Measures

Risk Variable	Mean (Std. Deviations) Ames 51 Unregulated	Ames 51 Regulated	Ames 80 Unregulated	Ames 80 Regulated
All Regulations:				
Synthetic	0.13 (0.34)	0.63 (0.49)	0.06 (0.25)	0.59 (0.50)
Ln (HERP Index)	-4.54 (5.26)	-6.42 (6.07)	-4.94 (4.70)	-6.32 (5.50)
FDA Regulations:				
Synthetic	0.29 (0.46)	0.88 (0.34)	0.17 (0.38)	0.77 (0.44)
Ln (HERP Index)	-4.73 (4.32)	-8.24 (7.90)	-5.70 (3.96)	-7.60 (8.02)
	Non-Synthetic	Synthetic	Non-Synthetic	Synthetic
All Regulations:				
Regulated	0.48 (0.51)	0.92 (0.28)	0.41 (0.50)	0.94 (0.25)
Ln (HERP Index)	-5.11 (4.05)	-6.64 (7.37)	-5.36 (4.05)	-6.45 (6.69)
FDA Regulations:				
Regulated	0.07 (0.27)	0.58 (0.50)	0.08 (0.28)	0.59 (0.50)
Ln (HERP Index)	-5.11 (4.05)	-6.64 (7.37)	-5.36 (4.05)	-7.93 (6.97)

Table 2

Logit Estimates of Regulation Probabilities*

Coefficient (Asymptotic Standard Error)

	Ames 51			Ames 80		
	1	2	3	4	5	6
Synthetic	2.8** (1.1)	2.8** (1.1)	3.1** (1.2)	3.3** (1.1)	3.5** (1.1)	3.5** (1.1)
HERP Index	--	0.005 (0.053)	--	--	9.9E-3 (79.1E-3	--
Mice Die	-1.4 (1.2)	--	--	-0.4 (0.8)	--	--
Rats TD_{50}	--	--	2.1E-4 (3.6E-4)	--	--	3.6E-4 (3.9E-4)
Mice TD_{50}	--	--	1.2E-4 (1.1E-4)	--	--	-0.6E-4 (1.2E-4)

*Equations 1-6 include an intercept, a dummy variable for whether rat and mice were tested, and equations 1 and 4 include a dummy variable for whether the rat tests were fatal. The standard errors of these variables are all larger than the estimated coefficients.

**Coefficients are statistically significant at the 95 percent confidence level, two-tailed test.